

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: ROBERT J. YATKA et al.

Serial No.: 10/712,114

Filing Date: November 13, 2003

For: METHOD OF CONTROLLING RELEASE OF  
N-SUBSTITUTED DERIVATIVES OF  
ASPARTAME IN CHEWING GUM AND GUM  
PRODUCED THEREBY

Examiner: Arthur L. Corbin

Group Art Unit No.: 1761

Confirmation No.: 7674

**DECLARATION UNDER 37 C.F.R. § 1.132**

I, David G. Barkalow, hereby declare:

1. I am employed by the Wm. Wrigley Jr. Company, the assignee of the above captioned application, as a senior principle scientist of the sweetener group in the Research and Development Department. I have worked at Wrigley for about 17 years. During the last 13 years I have worked in the field of sugarless coatings for chewing gum pellets, and am involved with high intensity sweeteners and carbohydrates and well as coatings.

2. I received a Bachelor's degree in chemistry from the University of Vermont in 1980 and a Ph.D. from the University of Wisconsin at Madison in forest products chemistry, with an emphasis on carbohydrate chemistry, in 1987. I then spent three years in post-doctoral work at Purdue University at the Whistler Center for Carbohydrate Chemistry.

3. I recently organized, supervised and participated in tests relating to the use of neotame (an N-substituted derivative of aspartame) in a coating on a chewing

gum pellet. As part of those tests, I supervised the production of a chewing gum pellet from a gum composition that is similar to gum compositions that are used to make gum centers for Wrigley's Eclipse® product. However, all high intensity sweeteners were removed from the center formula so as to not interfere with sensory testing of neotame sweetness. The gum centers were divided into three groups, and each group was coated with a different syrup, one producing a coating that contained 0.50% aspartame (APM), one that produced a coating that contained 0.014% neotame, and one that produced a coating that contained 0.05% neotame. The syrups were made according to the following formulas. A dry charge and flavor was used in the coating of each of the samples, as follows:

Lab Syrup Coating Formulas	Sample 1 0.50% Aspartame	Sample 2 0.014% Neotame	Sample 3 0.05% Neotame
Maltitol	750g	750g	750g
Water	155g	155g	155g
40% Gum Talha	256g	256g	256g
Aspartame	4.5g	0g	0g
Neotame	0g	0.13g	0.45g
Titanium Dioxide	11.8g	11.8g	11.8g
Maltitol Dry Charge	35g	35g	35g
Syrup solids, %	68-72	68-72	68-72
Temp., °C	70-75°C	70-75°C	70-75°C

Flavor for Coating (for 700g centers):
3.7g Peppermint flavor
2g Menthol

These products of Sample Nos. 2 and 3 were thus made by a process that falls within the scope of pending claims 26-27 and 31.

4. A 700 gram quantity of pillow shaped 1-gram centers was added to a 10-inch lab size coating pan and coated with maltitol syrup using a ladle. Room temperature air was blown onto the gum surface to dry the coating after each syrup application. After each of the first 8 syrup applications, about 4 grams of dry charge was applied until the 35 grams of maltitol was used. Menthol was dissolved in the peppermint flavor and half of the flavor blend was added after about 1/3 of the coating syrup had been applied. After the next 1/3 of coating, the second half of the flavor blend was added. The gum was coated to about a 1.5 gram piece size. No polishing agent was applied on these samples.

5. The samples were tested using an Employee Sensory Analysis (ESA), a common procedure used at Wrigley to demonstrate proof of hypothesis. In the neotame panel we originally had n=6 employees, including myself. However, two of the panelists did not have as much experience rating samples for bitterness, and their scores on a 10 point scale were quite far above those of the other panelists. Therefore all data from those two panelists were disregarded as being outliers. The results reported below are from the remaining four panelists. The samples were given to the panelists in a random order, so that there would be no order effect in the testing. The samples were coded with a three digit number so the employees did not know what the sample was. A sample ballot was filled out by each employee as the time was called out (a sample ballot is attached). Employees chewed a saltine cracker and drank water before evaluating the next sample.

6. The raw data from the tests was as follows:

**Sample No. 1 0.5% APM**

	Time (minutes)				
<b>Sweetness</b>	<b>0.5</b>	<b>1</b>	<b>2</b>	<b>4</b>	<b>6</b>
Panelist #1	6	6	6	4	3
Panelist #2	8	7	7	3	1
Panelist #3	6	6	5	3	2
Panelist #4	5	5	4	2	1
mean	6.3	6.0	5.5	3.0	1.8

<b>Flavor</b>	<b>0.5</b>	<b>1</b>	<b>2</b>	<b>4</b>	<b>6</b>
Panelist #1	8	7	6	3	3
Panelist #2	8	7	7	6	5
Panelist #3	9	8	8	8	8
Panelist #4	9	8	7	6	6
mean	8.5	7.5	7.0	5.8	5.5

<b>Bitterness</b>	<b>0.5</b>	<b>1</b>	<b>2</b>	<b>4</b>	<b>6</b>
Panelist #1	2	2	1	1	1
Panelist #2	1	1	1	1	2
Panelist #3	1	1	1	4	5
Panelist #4	2	2	4	5	5
mean	1.5	1.5	1.8	2.8	3.3

**Sample No. 2 0.014% Neotame**

	Time (minutes)				
<b>Sweetness</b>	<b>0.5</b>	<b>1</b>	<b>2</b>	<b>4</b>	<b>6</b>
Panelist #1	8	8	6	4	3
Panelist #2	7	5	4	2	1
Panelist #3	5	6	5	4	3
Panelist #4	6	6	4	2	1
mean	6.5	6.3	4.8	3.0	2.0

<b>Flavor</b>	<b>0.5</b>	<b>1</b>	<b>2</b>	<b>4</b>	<b>6</b>
Panelist #1	8	8	5	4	3
Panelist #2	9	8	7	6	5
Panelist #3	8	7	7	7	7
Panelist #4	8	8	7	7	6
mean	8.3	7.8	6.5	6.0	5.3

<b>Bitterness</b>	<b>0.5</b>	<b>1</b>	<b>2</b>	<b>4</b>	<b>6</b>
Panelist #1	2	2	1	1	1
Panelist #2	3	3	3	3	2
Panelist #3	2	3	4	5	7
Panelist #4	5	6	4	5	5
mean	3.0	3.5	3.0	3.5	3.8

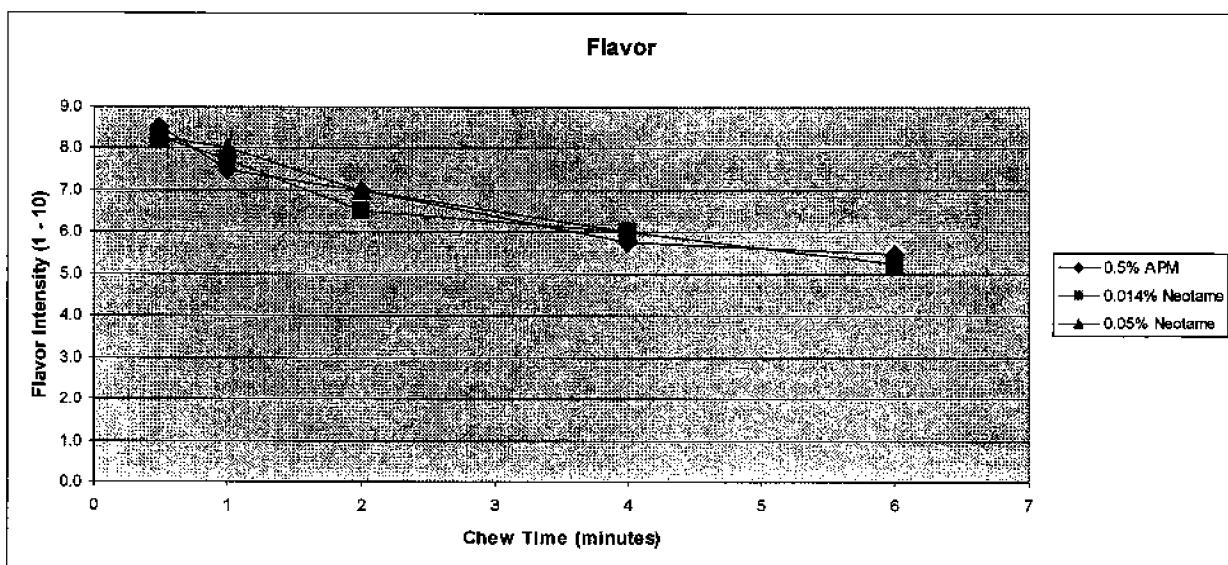
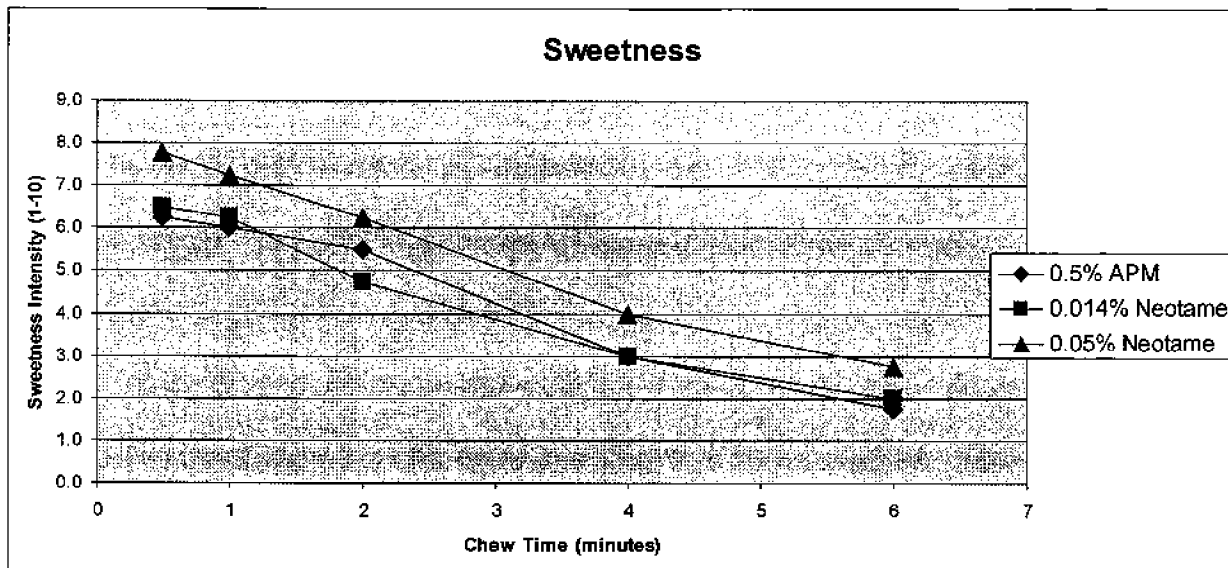
**Sample No. 3 0.05% Neotame**

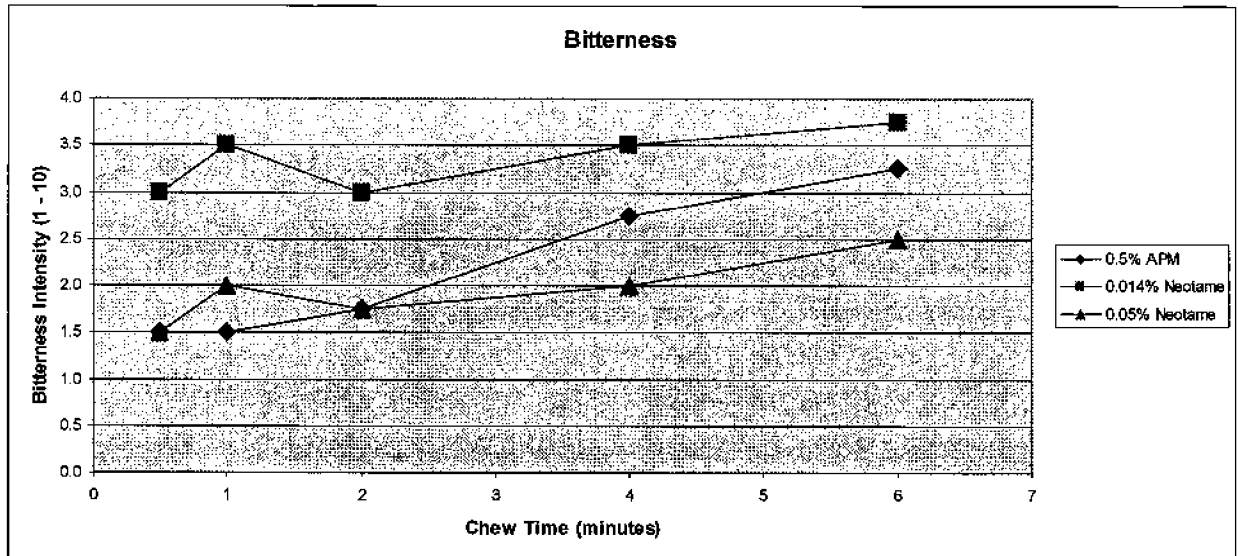
<b>Sweetness</b>	<b>0.5</b>	<b>1</b>	<b>2</b>	<b>4</b>	<b>6</b>
Panelist #1	7	7	6	4	4
Panelist #2	8	8	7	4	1
Panelist #3	7	8	7	6	5
Panelist #4	9	6	5	2	1
mean	7.8	7.3	6.3	4.0	2.8

<b>Flavor</b>	<b>0.5</b>	<b>1</b>	<b>2</b>	<b>4</b>	<b>6</b>
Panelist #1	8	7	6	4	3
Panelist #2	8	7	7	6	5
Panelist #3	8	9	8	7	7
Panelist #4	9	9	7	7	6
mean	8.3	8.0	7.0	6.0	5.3

<b>Bitterness</b>	<b>0.5</b>	<b>1</b>	<b>2</b>	<b>4</b>	<b>6</b>
Panelist #1	1	1	1	1	1
Panelist #2	2	1	1	1	1
Panelist #3	1	2	1	2	4
Panelist #4	2	4	4	4	4
mean	1.5	2.0	1.8	2.0	2.5

7. The mean test data is graphed below:





8. The sweetness and flavor levels in these results were what I expected. The theoretical isosweet level of APM at 0.5% and neotame at 0.014% gave similar sweetness and sweetness release. The higher level of sweetness with 0.05% neotame over 0.5% APM was also expected. The continuing reduction in flavor levels in all three samples was also expected. However, the bitterness results were unexpected. High intensity sweeteners would normally be expected to reduce bitterness by their nature as sweeteners. However, as the sweetener dissolves and is removed from the mouth, the bitterness reduction would normally diminish. This is because the flavor stays with the gum in the mouth and is released much more slowly than the sweetener. Thus, in the above noted tests, the mint flavor, which has bitter notes, is still being released after the sweetener is dissolved and removed from the mouth. Normally one would expect the slopes of the sweetness and bitterness to be inversely related.

9. However, from these tests I think there is a residual effect of neotame when used in a gum coating. With APM, there does not seem to be a residual effect of

reducing bitterness. The highest bitterness was noted in the isosweet level of neotame (0.014%) compared to APM at 0.5%. What was surprising was that the level of bitterness in the neotame samples did not increase as much as it did in the APM samples over time. Only a one unit increase was noted with both samples of neotame, whereas an increase of almost 2 units was noted for APM from 30 seconds to about 6 minutes. Thus it would appear that neotame can suppress bitterness much better than APM in a gum coating. It may be that neotame lingers in the mouth to reduce bitterness of bitter agents. This data shows that chewing gum centers coated with a coating that contains neotame has less of an increase in bitterness over time than chewing gum centers coated with a coating that contains APM, which is unexpected since the slopes of the sweetness for neotame and APM are similar.

10. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Signed: David G. Barkalow  
David G. Barkalow

Date: 10/31/07



## ESA PRODUCT DATA SHEET

NAME: \_\_\_\_\_

PANELIST NUMBER: \_\_\_\_\_

DATE: \_\_\_\_\_

PRODUCT CODE: \_\_\_\_\_

### Sweetness

Strong

30 sec	1 min	2 min	4 min	6 min
10	10	10	10	10
9	9	9	9	9
8	8	8	8	8
7	7	7	7	7
6	6	6	6	6
5	5	5	5	5
4	4	4	4	4
3	3	3	3	3
2	2	2	2	2
1	1	1	1	1

Weak

### Flavor

Strong

30 sec	1 min	2 min	4 min	6 min
10	10	10	10	10
9	9	9	9	9
8	8	8	8	8
7	7	7	7	7
6	6	6	6	6
5	5	5	5	5
4	4	4	4	4
3	3	3	3	3
2	2	2	2	2
1	1	1	1	1

Weak

### Bitterness

Strong

30 sec	1 min	2 min	4 min	6 min
10	10	10	10	10
9	9	9	9	9
8	8	8	8	8
7	7	7	7	7
6	6	6	6	6
5	5	5	5	5
4	4	4	4	4
3	3	3	3	3
2	2	2	2	2
1	1	1	1	1

Weak

Comments \_\_\_\_\_

\_\_\_\_\_